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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,280	03/04/2004	Michael R. Bowman	AM101023	3906
25291	7590	06/26/2008	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			06/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/792,280	Applicant(s) BOWMAN ET AL.	
	Examiner JERRY LIN	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,8,10,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments and amendments, filed March 20, 2008, have been fully considered and they are deemed to be persuasive in-part. The following rejections are newly applied as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1, 4, 6, 8, 10, 12, and 13 are under examination.

Claims 5, 7, 9, and 11 are withdrawn as being drawn to a non-elected group.

Election was made without traverse July 27, 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 4, 6, 8, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenberg et al. (US 2003/0166562) in light of Oh et al. (Biochemical and Biophysical Research Communications (2002) Volume 294, pages 1155-1160).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with airway subepithelial fibrosis and matrix deposition wherein the agent inhibits an activity or expression of a component of an arginine metabolic pathway that is not NOS.

Rothenberg et al. teach a method that includes administering a therapeutically effective amount of an agent to a mammal with asthma which inhibits CAT2 or the gene encoding for CAT2 (page 2, paragraphs 0016-0019); wherein one possible agent is capable of binding to a polynucleotide encoding the component by an antisense mechanism (page 12, paragraph 0069 - page 13, paragraph 0071); wherein another possible agent is lysine or a cationic polypeptide for inhibiting CAT2 (page 13, paragraph 0075, page 2, paragraph 13); where the mammal is human (page 2, paragraph 0016; page 4, paragraph 0041).

Oh et al. provides support that asthma is characterized by airway structural changes such as subepithelial fibrosis and extracellular matrix deposition in the airways (page 1155).

Thus, it would have been obvious to one of ordinary skill in the art that a method of providing an agent to a mammal with asthma would also necessarily be providing an agent to a mammal with subepithelial fibrosis and extracellular matrix deposition.

This rejection is necessitated by amendment.

Response to Arguments

4. Applicants have responded to the application of the reference by Rothenberg et al. by stating that he does not teach treating subepithelial fibrosis and extracellular matrix deposition. However, because asthma is characterized by subepithelial fibrosis and extracellular matrix deposition in the airways, administering an agent to a mammal with asthma would necessarily also be administering an agent to a mammal with subepithelial fibrosis and extracellular matrix deposition. Furthermore, Rothenberg et al. teach treating asthma with lysine. The instant specification shows that lysine is an agent that inhibits an activity of a component of an arginine metabolic pathway in a tissue affected by subepithelial fibrosis and extracellular matrix deposition. Therefore Rothenberg et al's administration of lysine to a mammal with asthma is necessarily a teaching of administering an agent to tissue affected by subepithelial fibrosis and extracellular matrix deposition.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenberg et al. (US 2003/0166562) in light of Oh et al. (Biochemical and Biophysical Research Communications (2002) Volume 294, pages 1155-1160) as applied to claims

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1, 4, 6, 8, 12 and 13 above, and further in view of Hannon (Nature (2002) volume 418, pages 244-251).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with airway subepithelial fibrosis and matrix deposition where an agent such as siRNA inhibits the activity or expression of a component of an arginine metabolic pathway and where the component is not a nitric oxide synthase.

Rothenberg et al. in light of Oh et al. is applied as above.

However Rothenberg et al. do not specifically teach using siRNA.

Regarding claim 10, Hannon teaches that siRNA may be synthesized to target and silence genes of interest (page 245; page 250).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of Rothenberg et al. in light of Oh et al. with Hannon to administer siRNA for the purpose of inhibiting the production of CAT2. Rothenberg et al. teach that the inhibition of CAT2 expression via antisense mechanisms is desirable to treat asthma (page 14, paragraphs 0082 and 0091; page 16, paragraph 0012).

However, Hannon teaches that siRNA is a much more potent inhibitor of gene expression than sense or antisense RNAs (page 244, right column). Thus one of ordinary skill in the art seeking to inhibit CAT2 mRNA would be motivated to use siRNA for the increased potency of siRNA over sense or antisense RNAs.

This rejection is necessitated by amendment.

Response to Arguments

6. Applicants have responded to using the combination of Rothenberg et al. and Hannon by relying on their arguments to Rothenberg et al. Please see above for the Examiner's Response.

Withdrawn Rejections

7. Applicant's arguments and amendments, filed July 12, 2007, with respect to the rejection of claims 1, 4, 6, 12, 13, and 21-24 under 35 U.S.C. §103 as being unpatentable over Ochoa et al. in light of Jeffery are persuasive. Ochoa et al. and Jeffery do not teach treating subepithelial fibrosis and matrix deposition. This rejection is withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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